UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,405	11/18/2005	Motonori Miyakawa	Q85416	8028

23373 7590 02/13/2007

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
GALLIS, DAVID E	
ART UNIT	**PAPER NUMBER**
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,405	MIYAKAWA ET AL.	
	Examiner	Art Unit	
	David E. Gallis	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 through 13 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 through 5 (in part), drawn to a tetrahydroquinoline derivative represented by formula (I), wherein R1=NO2, R2=H, X=C, Y=C(CH3)2, and n=0.

Group II, claim(s) 1 through 5 (in part), drawn to a tetrahydroquinoline derivative represented by formula (I), wherein R1=NO2, R2=H, X=O, Y=C(CH3)2 and n=0. If this invention is selected an election with respect to Z, as specified in claim 1, must be made from the following: Z=unsubstituted or substituted phenyl, or Z=unsubstituted or substituted heteroaryl, or Z=unsubstituted or substituted alkyl, or Z=-(CO)-substituted phenyl, or Z=-O-substituted phenyl, or Z=-NH- or –N(CH3)- substituted phenyl.

Group III, claim(s) 1 through 5 (in part), drawn to a tetrahydroquinoline derivative represented by formula (I), wherein R1=CN, R2=H, X=O, Y=C(CH3)2 and n=0.

Group IV, claim(s) 1 through 5 (in part), drawn to a tetrahydroquinoline derivative represented by formula (I), wherein R1=CN, R2=H, X=C, Y=C(CH3)2 and n=0. If this invention is selected an election with respect to Z, as specified in claim 1, must be made from the following: Z=unsubstituted or substituted phenyl, or Z=unsubstituted or substituted heteroaryl.

Group V, claim(s) 1 through 5 (in part), drawn to a tetrahydroquinoline derivative represented by formula (I), wherein R1=CN, R2=H, X=O, Y=C(CH3)2 and n=0. If this invention is selected an election with respect to Z, as specified in claim 1, must be made from the following: Z=unsubstituted or substituted phenyl, or Z=unsubstituted or substituted heteroaryl.

Group VI, claim(s) 1 through 5 (in part), drawn to a tetrahydroquinoline derivative represented by formula (I), wherein R1=CN, R2=H, X=O, Y=CH2 or CH(CH3) and n=0.

Group VII, claim(s) 1 through 5 (in part), drawn to a tetrahydroquinoline derivative represented by formula (I) and not specified by the geneses of inventions I through VI or the species therein where election is required. If this group is selected, further restriction may be required.

Group VIII, claim(s) 6 through 10 (in part), drawn to a pharmaceutical comprising the tetrahydroquinoline derivative according to formula (I) (claims 1 to 5) as an active ingredient for the prevention or treatment of a disease. If this invention is selected an election is required with respect to the diseases of osteoporosis, male hypogonadism, male sexual dysfunction, abnormal sex differentiation, male delayed puberty, cancer in female genital organ, breast cancer, mastopathy, endometriosis, female sexual dysfunction, and hematopoietic dysfunction.

Group IX, claim(s) 11 through 13 (in part), drawn to a method of preventing or treating a disease comprising administering the tetrahydroquinoline derivative according to formula (I) (claims 1 to 5) in an effective amount. If this invention is selected an election is required with respect to the diseases of osteoporosis, male hypogonadism, male sexual dysfunction, abnormal sex differentiation, male delayed puberty, cancer in female genital organ, breast cancer, mastopathy, endometriosis, female sexual dysfunction, and hematopoietic dysfunction.

3. The inventions listed as Groups I through IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I through IX lacks novelty as a tetrahydroquinoline derivative. Hayes et al. teach a tetrahydroquinoline derivative wherein with respect to the instant formula (I) R1=NO2 or CN, X=C, n=0 and the Y-N(R2)[(CO)Z] equivalent is C2-C10 substituted alky (See Hayes et al, US 5,925,527, 20 July 1999, columns 3 and 4.) This demonstrates lack of novelty with respect to the compound claimed.

Therefore a technical feature linking the inventions of Groups I through IX do not constitute a special feature as defined by PCT Rule 13.2 as it does not define a contribution over prior art.

Accordingly, Groups I through IX are not linked by the same or a corresponding special technical feature as to form a general inventive concept

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
The species are fined above within the descriptions of Inventions II, IV, V, VII, VIII, and IX.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims and species deemed to be in correspondence are listed above in their relevant invention groups.

6. The species lack unity because they differ in elements, bonding arrangements and chemical structure to such an extent that a reference anticipating any one group would not render the other group obvious, thus unpatentability of any group would not necessarily imply unpatentability of another group. The varying classes and subclasses of each diverse structure as delineated will constitute an enormous search burden.

7. The following claim(s) are generic: Claims 1 through 8, 10, 11, and 13.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Fri 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Cecilia Tsang or Andrew Wang can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David E. Gallis
Patent Examiner

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600